K002509

2 510 (k) Summary

Establishment: BrainLAB AG
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Reg. Nr. 804 39 33

Contact: Stefan Vilsmeier
President and CEO

Summary Date: 08/03/2000

Classification name: Novalis Shaped Beam Surgery™ System

Device Description: The Novalis Shaped Beam Surgery™ System for Radiosurgery and stereotactic Radiotherapy is a dedicated treatment planning and treatment delivery system for the treatment of cranial and extracranial targets. The dose delivery system comprises a computer controlled 6 MV photon beam at up to 800 cGy per minute and an integrated, automated photon beam shaping system generating a maximum field size of 10x10cm TSD. The system also includes conical fixed beam collimators for traditional radiosurgery. A precision computer controlled treatment table with mount for headring provides positioning of the patient. A non-invasive repeat fixation system allows stereotactic fractionated treatments. A headring, a target positioning system for precision patient treatment setup and an automated patient positioning system ensure stereotactic alignment of the patient.
The Novalis treatment planning software generates 3D reconstruction of the patient anatomy. CT and MR images will be fused automatically and allow incorporation of non-localized images. The treatment planning software allows either static or dynamic Shaped Beam radiosurgery, using the inherent beam shaping device, or traditional radiosurgery.
The patient documentation software comprises patient registration, diagnosis module, prescription module, history of actual treatment and delivery system radiosurgery setup parameters.
The safety and effectiveness of the Novalis system has been shown by the corresponding verification and validation procedures and the Novalis system can be used within its intended use.

Intended use: Novalis is intended to be used as a dedicated system to plan, to perform and to document radiosurgery or stereotactic radiotherapy for lesions (e.g. arteriovenous malformations), tumors, head and neck targets, functional disorders and extracranial indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Stefan Vilsmeier
President and CEO
BrianLAB AG
AmmerthalstraBe 8
85551 Heimstetten
Germany

Re: K002509
Novalis (Shaped Beam Surgery™ System)
Dated: August 4, 2000
Received: August 15, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE & 90 MUJ

Dear Mr. Vilsmeier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002509

Device Name: **Novalis (Shaped Beam Surgery™ System)**

Indications For Use:

Novalis Shaped Beam Surgery™ System

Novalis is intended to be used as a dedicated system to plan, to perform and to document radiosurgery or stereotactic radiotherapy for lesions (e.g. arteriovenous malformations), tumors, head and neck targets, functional disorders and extracranial indications .

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format I-2-96)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002509